DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

946521

APR 23 2004

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Gun Ho Bea
Chief Executive Officer
Bescon Co., Ltd.
398-4 Doojung-dong
Chunan-City, Chungham
KOREA

Dear Mr. Bea:

During an inspection of your firm located in Chunan-City, Chungham, Korea, on November 24-27, 2003, our investigator determined that your firm manufactures daily wear soft contact lenses. These products are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to, the following:

1. Failure to validate with a high degree of assurance a process that cannot be fully verified by subsequent inspection and test, and to document and approve the activities and results of the validation, as required by 21 CFR § 820.75(a). For example:

   - Your firm failed to adequately validate the terminal steam autoclave sterilization process.

     - o There was no validation protocol or procedure for the original sterilization validation.
     - o There was no evidence that the sterilization process validation had any established acceptance criteria prior to validation efforts.
     - o The validation study documentation discussed the results of bio-indicators placed in the autoclave during the validation study, but the documentation did not establish if there were positive or negative controls utilized in the study.
     - o There was no documentation that the sterilization validation results were acceptable and approved.

- Your firm failed to validate the foil sealing process, which cannot be fully verified through visual inspection.

  - o There was no validation protocol or procedure.
  - o There was no evidence that all of the appropriate variables for the sealing process were controlled (i.e., sealing processes typically require the monitoring and control of parameters for pressure and time, as well as temperature).
  - o There was no evidence of temperature, which was considered by your firm to be the critical parameter for this process, being monitored and controlled. In addition, according to Mr. Yoo, the last time the temperature was verified was approximately two years ago.

2. Failure to establish and maintain adequate acceptance procedures, which include inspections, tests, or other verification activities, to ensure that specified requirements for your firm's devices are met, as required by 21 CFR § 820.80(a). In addition, there was a failure to document acceptance activities to include the activities performed, the dates the activities were performed, the results and the signature of the person conducting the activities, as required by 21 CFR § 820.80(e). For example:

   - Your work instructions require that the thickness of the lenses be measured at [redacted] distinct points for [redacted] lenses every [redacted]. Evidence shows that this acceptance activity was performed for only the first [redacted] of production. Further, this acceptance activity was not adequately documented and the raw data is not retained after the data are transcribed onto device history records.

   - Your work instructions require that [redacted] of the lenses are to be measured for proper diopter. There is no documentation that this acceptance activity was performed.

   - Your work instructions require that [redacted] of the lenses are to be inspected to ensure that there are no vapor vacuoles in the lenses. There is no documentation that this acceptance activity was performed.

3. Failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specification, as required by 21 CFR § 820.70(a). For example:

- Your work instructions require that the [redacted] cartridge water filter used in the water distillation process be changed when the pressure differential has increased by [redacted] or [redacted]. The firm does not monitor pressure differential and there is no documentation that the firm changes the water filter once per month.

- There is no documentation that the [redacted] filter is tested for integrity after installation, as recommended by the filter manufacturer.

We received a response from Martin Dalsing, US Agent, Bescon, dated January 12, 2004, concerning our investigator's observations noted on the FDA-483. It appears that the response is inadequate. Your firm promises that corrections have been implemented, or will be implemented by May 31, 2004; however no documentation was provided to support this assertion.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. United States federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all devices manufactured by the Bescon Co., Ltd., Chunan-City, Chungham, Korea, facility may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected. In order to prevent your devices from being detained without physical examination, your firm will need to respond to this Warning Letter and correct the violations noted in this letter. In addition, the agency usually needs to conduct a follow-up inspection to verify that appropriate corrections have been implemented.

Please notify this office in writing of the specific steps you have taken to correct the above-noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to

assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement A, Dental, ENT & Ophthalmic Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Mr. Ronald L. Swann.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Ernest N. Smith at the letterhead address or via telephone at (301) 594-4613 or via FAX at (301) 594-4638.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health

cc:
Mr. Martin Dalsing
US Agent, Bescon
Medvice Consulting, Inc.
623 Glacier Drive
Grand Junction, Colorado 81503